

REMARKS

Election/Restriction:

Applicants acknowledge the Examiner's entry of the restriction requirement. Applicants respectfully maintain their traversal of the restriction requirement. In order to expedite prosecution, Applicants have withdrawn claim 17. Applicants thank the Examiner for inclusion of claim 29 in the examination upon allowance of generic claim 25.

In the Drawings:

The Examiner objected to the drawings under 37 CFR 1.83(a) for failing to show the needle and the cannula as separate elements. Applicants have amended FIG. 7 to include the numeral 126. FIGS. 6-10 show the cannula 126 as a separate element. In FIG. 11, as originally submitted, the cannula and the infusion set are shown as separate elements providing support for the amendments to FIGS. 6-10. For clarity, Applicants have shown the cannula 126 surrounding the needle prior to insertion into the skin. FIG. 11 has been amended to show the infusion set placed on the skin, the cannula is inserted in the skin and not visible. The transcutaneous placement of the cannula 126 is shown in FIG. 11. The insertion needle 112 secured to the plunger 130 of the infusion set 114 is shown removed from the cannula in FIG 11.

Applicants respectfully assert that the newly amended FIGS. 7 and 11 show the structural details essential for a proper understanding of the disclosed invention under MPEP §608.02 (d).

Therefore, Applicants respectfully request that the Examiner withdraw the objection to the drawings under 37 CFR 1.83 (a).

The Examiner objected to the drawings under 37 CFR 1.84 (p)(4) because the character "113" has been used to designate both the infusion tubing set and spring (see FIGS. 6-8). Applicants respectfully assert that the element 113 represents infusion tubing wound around the plunger as indicated on page 10, line 27. The spring is represented by element 136, shown and described on page 11, lines 17-20, wherein the spring 136 may comprise a number of elongated plastic strips 136.

Therefore, Applicants respectfully request that the Examiner withdraw the objection to the drawings under CFR 1.84 (p)(4) because element 113 refers to the infusion tubing and the element 136 refers to the spring.

The Examiner objected to the drawings because the elements 113 and 136 are confusing in the drawings because it is not clear and consistent if they are a spring or a strip as shown in FIGS. 6-8 and 12 and none of the drawings for FIGS. 6-11 show where the transverse cut is located for FIG. 12.

Applicants respectfully traverse the Examiners objection. As discussed above, element 113 represents infusion tubing and element 136 represents the spring. Applicants have amended FIG. 8 to indicate where the transverse cut for FIG. 12 is located.

Therefore, Applicants respectfully request that the Examiner withdraw the objection to the drawings.

In the Claims:

Claims 1-16 and 18-30 are pending in this application. New claims 31-45 have been added herein. Favorable reconsideration is requested.

In this paper, Applicants have amended Claims 10, 13, 19, and 23-25. No new matter has been added. Claims 10, 19, 24, and 25 have been amended to provide antecedent basis. Claims 13 and 23 have been amended to include all the limitations of the base claim and any intervening claims and rewritten in independent form. Claim 25 has further been amended to accurately claim the invention described in the specification and the figures. Support for the amendment to claim 25 may be found throughout the specification and on page 3, lines 26-32.

Applicants have added new dependent claims 31-45. No new matter has been added. Support for the newly added claims may be found throughout the specification and in the figures.

I. Rejections under 35 USC §112

The Examiner rejected claims 10, 19, 24-30 under 35 USC § 112, second paragraph. According to the Examiner, claim 24 has no antecedent basis for “the strips”, claim 25 has no antecedent basis for “the drive”, and claims 10 and 19 have no antecedent basis for “the plunger head”.

Applicants have amended claims 10, 19, 24, and 25 to provided antecedent basis. Claim 24 has been amended to depend from claim 23 which claims “a number of individual, elongated flexible plastics strips (136)”, thereby providing antecedent basis for “the strips” in claim 24.

Applicants have amended claim 25 to provide antecedent basis by amending “a spring” to “a drive”. Support for the amendment to claim 25 may be found through out the specification and on page 11, line 11. Claims 26-30 depend from newly amended claim 25 and therefore also have proper antecedent basis.

Applicants have amended claim 10 to provide proper antecedent basis for the term “the plunger head”. Claim 19 has been amended to remove the term “head”.

Support for the amendment to claims 10 and 19 may be found through out the specification and on page 7, lines 21-24.

Accordingly, Applicants respectfully request that the Examiner withdraw the §112 rejections.

II. Claim rejections under 35 USC §102(e)

The Examiner rejected claims 1-12, 16, and 18-22 under 35 USC §102(e) as being anticipated by Safabash et al. (US 6,293,925). The Examiner states that Safabash et al. disclose an insertion device 10, 110 (FIGS. 1-29), having a housing 28, 128, a plunger 30, 130 having substantially non-detachable secured thereto an insertion needle in hub 18, a drive 38, 138 or 54, 154. The plunger head includes a safety retainer 202. FIGS. 40a-40d show a cover for covering the infusion set and another cover to cover the insertion needle.

Applicants respectfully traverse the Examiner's rejection based on Safabash et al. Applicants respectfully request reconsideration of the rejected claims in light of the traversals discussed below.

Safabash et al. disclose an injector or insertion device 10 for inserting an insertion needle 12 of an insertion set 14 through the skin 16 of a patient. (Col. 8, lines 17-28.) The injector 10 comprises a cylindrical forward barrel 28 (or device housing) having a plunger 30 (or carrier body) mounted therein for longitudinal sliding movement within a hollow bore between a forward advanced position and a rearward retracted position. (Col. 9 lines 6-11.) The plunger 30 has a head 32 at a forward end thereof for **releasably** receiving and retaining the subcutaneous insertion set 14. (Col. 9, lines 11-13.) With respect to the insertion set 14 for infusing medical fluids to a patient, the insertion needle 12 is connected to a hub 18 at a rear or proximal end thereof, and protrudes through a housing 20 of the insertion set 14. (Col. 8, lines 47-51.) In the embodiments taught by Safabash et al., the insertion *needle itself* is part of the insertion set which is **releasably** received at the plunger.

In contrast, Applicants' invention for an injector device for placing a subcutaneous infusion set comprises an insertion needle that is substantially non-detachably secured to the plunger. The plunger has a generally cylindrical form with a head and a central pin including a metal insertion needle secured thereto in a molding

process, by press-fit, or by any other method providing a suitable resistance to loss of the insertion needle during use of the device (page 10, lines 19-22). Each of the independent claims 1 and 18 recites the requirement for the plunger (30, 130, 230) having substantially non-detachably secured thereto an insertion needle (12, 112, 212). The plunger claimed by Applicants, having substantially non-detachably secured thereto an insertion needle, is not taught by Safabash et al. which teaches a releasable insertion needle attached to and part of the infusion set.

Thus, Applicants assert that the claimed invention is not anticipated by Safabash et al. Applicants respectfully request the rejection of claims 1-12, 16, and 18-22 under 35 USC §102(e) be withdrawn.

Allowable Subject Matter

Applicant gratefully acknowledges the Examiner would allow Claims 13-15 and 23 if rewritten in independent form including all the limitations of the base claim and any intervening claims. Claim 24 would be allowable if rewritten to overcome the rejection under 35 USC §112, second paragraph and to include all of the limitations of the base claim and any intervening claims. Claims 25-30 would be allowable if rewritten or amended to overcome the rejections under 35 USC §112, second paragraph.

Claims 13, 23, 24 and 25 have been amended to put the claims in condition for allowance. Applicants have amended claim 13 to include all the limitations of claim 1 and claim 12 rewritten in independent form. Claims 14 and 15 depend from newly amended claim 13.

Applicants have amended claim 23 to include all the limitations of claim 18 and rewritten in independent form. Claim 24 has been amended to depend from newly amended claim 23 and therefore includes all the limitations of the base claim 18, the intervening claim 23, and to provide antecedent basis for "the strips".

Claim 25 has been amended to provide antecedent basis for "the drive" by amending the term "the drive" to "the drive spring" and the term "a spring" to "a drive spring". Claims 26-30 depend from newly amended claim 25.

Applicants assert that the newly amended claims 13, 23, 24, and 25, and claims 1-12, 14-16, 18-22, 26-45 are in condition for allowance. Early notification to such effect is earnestly solicited.

SUMMARY

Pending Claims 1-16 and 18-30 as amended are patentable. New claims 31-45 are also patentable. Applicant respectfully requests the Examiner grant early allowance of this application. The Examiner is invited to contact the undersigned attorney for the Applicants via telephone if such communication would expedite this application.

Respectfully submitted,

A handwritten signature in cursive script, reading "Heidi A. Dare", is written over a horizontal line.

Heidi A. Dare
Registration No. 50,775
Attorney for Applicant

BRINKS HOFER GILSON & LIONE
P.O. BOX 10395
CHICAGO, ILLINOIS 60610
(312) 321-4200